Results of Testing

Chemical Name	CAS No.	Study Code/Type	Protocol/Guideline	Species	Exposure	Dose/Concentration	No. per Group	Results	Reference
Nitrobenzene	98-95-3	HECTOXCARC Carcinogenicity	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	F344 rats	inhalation, 6 hr/day, 5 d/wk for 107 weeks	0, 1, 5, 25 ppm	Not reported	The test substance was determined to be carcinogenic. In male rats, the incidence of hepatocellular adenoma, hepatocellular adenoma or carcinoma, and renal tubular adenoma were increased. In addition, male rats had a marginally increased incidence of thyroid follicular neoplasia (adenoma or adenocarcinoma). In females, the incidence of endometrial stromal polyp was increased. Exposure was also associated with increased incidence of nasal mucosa, blood, liver and testis effects. Other toxic effects noted included methemoglobinemia and hepatic effects.	Docket# OPPTS-47044, Chemical Industry Institute of Toxicology (CIIT)
Nitrobenzene	98-95-3	HECTOXCARC Carcinogenicity	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	CD rats (male)	inhalation, 6 hr/day, 5 d/wk for 107 weeks	0, 1, 5, 25 ppm	Not reported	The test substance was determined to be carcinogenic. In male rats, the incidence of hepatocellular adenoma and hepatocellular adenoma or carcinoma were increased. Exposure was also associated with increased incidence of nasal mucosa, blood, liver and testis effects. Other toxic effects included methemoglobinemia, hepatic effects, and testicular atrophy.	Docket# OPPTS-47044, CIIT
Nitrobenzene	98-95-3	HECTOXCARC Carcinogenicity	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	$B6C3F_1$ mice	inhalation, 6 hr/day, 5 d/wk for 107 weeks	0, 5, 25, 50 ppm	Not reported	The test substance was determined to be carcinogenic. In male mice, the incidence of alveolar/bronchiolar adenoma, alveolar/bronchiolar carcinoma, and thyroid adenoma were increased. In female mice, the incidence of mammary gland adenocarcinoma was increased and a marginally increased incidence of hepatocellular adenoma. Exposure was also associated with increased incidence of nasal mucosa, blood, liver and testis effects. Other toxic effects included methemoglobinemia, hepatic effects, and testicular atrophy.	Docket# OPPTS-47044, CIIT
Nitrobenzene	98-95-3	HEGTOXCHRM Chromosomal aberration	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	chinese hamster (ovary cells)	*in vitro*, with and without metabolic activation	#1600 µg/ml in DMSO	Not applicable	Test results were negative, with and without S9 metabolic activation.	National Toxicology Program (NTP) unpublished results
Nitrobenzene	98-95-3	HEGTOXDNAF Sister chromatid exchange	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	chinese hamster (ovary cells)	*in vitro*, with and without metabolic activation	#1600 µg/ml in DMSO	Not applicable	Test results were negative, with and without S9 metabolic activation.	NTP unpublished results.
Nitrobenzene	98-95-3	HEGTOXMUTA Mutagenicity	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	*Salmonella*	*in vitro*, with and without metabolic activation	up to 1000 µg/plate	Not reported	Test results indicate nitrobenzene is not a gene mutagen in the Salmonella/Ames test both with and without metabolic activation in strains TA98, TA100, TA1535, TA1537.	Haworth, S, T Lawlor, K Mortelmans, W Speck and E Zeiger. 1983. Environmental Mutagenesis 5(Suppl. 1):23-142.

Chemical Name	CAS No.	Study Code/Type	Protocol/Guideline	Species	Exposure	Dose/Concentration	No. per Group	Results	Reference
Nitrobenzene	98-95-3	HERTOXTERA Teratogenicity study	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	rats	inhalation, 6 hr/d, 5 d/wk for 10 weeks, treatment continued with 6 hr/d, 7 days/wk for 2-wk mating period, a 19-day gestation period (females only), and 17-day postpartum period (dams only)	0, 1, 10, 40 ppm	30/sex/group	Treatment with the test substance compromised the reproduction of rats at 40 ppm, due to toxic effects in the testes of males. The NOEL was established at 10 ppm regarding reproduction and fertility in rats.	OTS0510653, The Nitrobenzene Association Project Report 47-524
Nitrobenzene	98-95-3	HERTOXTERA Teratogenicity study	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	rats	inhalation, gestation days 6-15	0, 1, 10, 40 ppm	Not reported	There was no maternal, embryo or fetotoxicity at 1 ppm, and no embryo or fetotoxicity (including teratogenicity) at 10 and 40 ppm, although these concentrations produced some maternal toxicity.	OTS0510652, The Nitrobenzene Association Project Report 47-522
Nitrobenzene	98-95-3	HERTOXTERA Teratogenicity study	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	rabbits	inhalation, 6 hr/d on gestation days 7-19	10, 40, 100 ppm	22/group	At 10 ppm, the test substance produced no maternal toxicity, embryotoxicity or teratogenicity. At 40 ppm, the test substance produced some maternal toxicity (increased methemoglobin levels and increased liver weights); however, no embryotoxicity or teratogenicity was indicated. At 100 ppm, the test substance produced maternal toxicity (increased methemoglobin levels and liver weights) and some embryotoxicity (increased resorption data); however, no teratogenicity was indicated.	OTS0510651, The Nitrobenzene Association Project Report 83-2725
Nitrobenzene	98-95-3	HESTOX Subchronic toxicity	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	CD (Sprague-Dawley) rats	inhalation, 6 hr/day, 5 d/wk for 90 days	0, 5, 16, 50 ppm	Not reported	There was no effect on body weight gain or mortality. Mean serum methemoglobin concentrations were significantly elevated in 16 and 50 ppm male rats and 50 ppm female rats. The liver was affected (centrilobular hepatocyte hypertrophy) in rats. The testicles had bilateral degeneration of seminiferous epithelium and a reduction or absence of sperm in the epididymis.	Docket# OPPTS-47044, CIIT
Nitrobenzene	98-95-3	HESTOX Subchronic toxicity	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	F-344 rats	inhalation, 6 hr/day, 5 d/wk for 90 days	0, 5, 16, 50 ppm	Not reported	There was no effect on body weight gain or mortality. Mean serum methemoglobin concentrations were significantly elevated in 5, 16, and 50 ppm male rats and 16 and 50 ppm female rats. The liver was affected (centrilobular necrosis and disorganization of hepatic cord) at 50 ppm. The testicles had bilateral degeneration of seminiferous epithelium and a reduction or absence of sperm in the epididymis.	Docket# OPPTS-47044, CIIT
Nitrobenzene	98-95-3	HESTOX Subchronic toxicity	Non-TSCA Protocol/ Guideline (see docket# OPTS-47004)	$B6C3F_1$ mice	inhalation, 6 hr/day, 5 d/wk for 90 days	0, 5, 16, 50 ppm	Not reported	There was no effect on body weight gain or mortality. Mean serum methemoglobin concentrations were significantly elevated in 50 ppm rats. Cellular vacuolization of the zona reticularis of the adrenal was found in females at 5 ppm, and increased in severity with dose. Male mice has increased severity of liver lesions (centrilobular hepatocyte hyperplasia).	Docket# OPPTS-47044, CIIT